UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

LOGAN M. SCHMIDT, Plaintiff, vs. BOSTON SCIENTIFIC CORPORATION, *et al*., Defendants.	CASE NO. 5:15CV00488 JUDGE JOHN R. ADAMS **ORDER AND DECISION** (Resolving Doc. 31, 33)

This matter is before the Court on two motions to dismiss filed by Defendant Medtronic, Inc. ("Medtronic") and Defendants Boston Scientific Corporation and Guidant LLC (collectively "Boston Scientific"). Docs. 31, 33. Pursuant to Fed.R.Civ.P. 8 and the Supreme Court's holdings in *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*, this Court finds that Plaintiff Logan Schmidt has failed to plead the requisite facts and elements necessary to state parallel claims for defective design, manufacture, formulation, construction, and inadequate warning of a Class III medical device. Furthermore, Schmidt has failed to sufficiently plead a claim for supplier liability. Finally, Schmidt's claims for common law negligence are preempted by federal law and abrogated by Ohio statute. As such, this Court hereby DISMISSES Schmidt's Amended Complaint.

I. FACTS AND PROCEDURAL HISTORY

Schmidt has had a number of medical procedures since childhood for his heart, including implantation of Implantable Cardioverter Defibrillators ("ICDs") and their components, including leads and shocking coils. Doc. 27. Schmidt believes these medical devices were manufactured, designed, and distributed by Medtronic, Boston Scientific and Doe Entities 1-3. Doc. 27. Consequently, he then filed the underlying lawsuit in the Stark County, Ohio Court of

Common Pleas, alleging damages from a short-circuit in 2009 of a lead, electrical coil, or its component. The original Complaint set forth five causes of action:

1) Products Liability Defective Design, Manufacture, Formulation, Construction, "brought pursuant to Ohio Revised Code § 2307.75 *et seq.*"

2) Products Liability – Inadequate Warning, "brought pursuant to Ohio Revised Code § 2307.75 *et seq.*"

3) Products Liability – Supplier Liability, "brought pursuant to Ohio Revised Code § 2307.78 *et seq.*"

4) Negligence – Inadequate Warning, brought pursuant to Ohio common law.

5) Negligence – Defective Design/Manufacture, brought pursuant to Ohio common law.

Doc. 1-1.

Boston Scientific later removed the case to federal court. Medtronic and Boston Scientific then filed motions to dismiss under Fed.R.Civ.P. 8(a) and 12(b)(6). Schmidt filed a response and sought leave to amend the Complaint, which was granted. Schmidt filed an Amended Complaint alleging the same causes of action, but including additional details such as device identification numbers. Doc. 27. Medtronic and Boston Scientific re-filed their motions to dismiss, arguing the following:

1) Schmidt failed to sufficiently plead his claims for relief;

2) Schmidt's claims are preempted by federal law and Schmidt has failed to satisfy the narrow exception of state law claims; and,

3) Schmidt's common law negligence claims are barred by the Ohio Products Liability Act.

Docs. 31, 33. Medtronic and Boston Scientific's motions raise the same issues and will therefore be addressed together. After reviewing the briefing in the matter, the Court finds the motions are well-taken.

II. LAW AND ANALYSIS

A. Legal Standard

The Supreme Court has set forth the standard for a motion to dismiss under Rule 8 as follows:

> We turn to respondent's complaint. Under Federal Rule of Civil Procedure 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." As the Court held in *Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929, the pleading standard Rule 8 announces does not require "detailed factual allegations," but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. *Id.*, at 555, 127 S.Ct. 1955 (citing *Papasan v. Allain*, 478 U.S. 265, 286, 106 S.Ct. 2932, 92 L.Ed.2d 209 (1986)). A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." 550 U.S., at 555, 127 S.Ct. 1955. Nor does a complaint suffice if it tenders "naked assertion[s]" devoid of "further factual enhancement." *Id.*, at 557, 127 S.Ct. 1955.
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> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Id.*, at 570, 127 S.Ct. 1955. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.*, at 556, 127 S.Ct. 1955. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. *Ibid.* Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.' " *Id.*, at 557, 127 S.Ct. 1955 (brackets omitted).
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> Two working principles underlie our decision in *Twombly*. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. *Id.*, at 555, 127 S.Ct. 1955 (Although for the purposes of a motion to dismiss we must take all of the factual allegations in the complaint as true, we "are not bound to accept as true a legal conclusion couched as a factual allegation" (internal quotation marks omitted))… Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.

Ashcroft v. Iqbal, 556 U.S. 662, 677-79 (2009).

B. Insufficient Pleading to State a Claim

It is undisputed that the equipment that forms the basis of Schmidt's claims are Class III medical devices under 21 U.S.C. §360c(a)(1)(C).[1] It appears from the pleadings and the briefing that the parties do not dispute that the 1938 Food, Drug, and Cosmetic Act, as amended ("FDA") exclusively enforces Class III device requirements. Although "citizens may report wrongdoing and petition the agency to take action," there is no private right of action under the FDA in the event a violation is uncovered. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001). However, individuals may assert certain state law claims related to the devices as long as they are considered "parallel claims," that is, as long as they assert a claim for damages premised on a violation of the FDA regulations that are not "different from, or in addition to" the requirements imposed by federal law. *Reigel*, 552 U.S. at 330, *citing Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

Armed with the Supreme Court's ruling in *Reigel*, courts have held that "[p]arallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that '[the] defendant

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[1] In 1976, Congress enacted the Medical Device Amendments ("MDA") to the 1938 Food, Drug, and Cosmetic Act ("FDA"), in order to "provide for the safety and effectiveness of medical devices intended for human use." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 108 (2nd Cir. 2006), *aff'd by Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008). Those devices for which "'general controls' and 'special controls' are insufficient to provide reasonable assurance of safety and effectiveness, and which either 'present a potential unreasonable risk of illness or injury' or are 'for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health' are classified as Class III devices." *Id.* at 109 (*citing*21 U.S.C. § 360c(a)(1)(C)).

> To market a Class III device within the United States, the manufacturer must either submit its product to the FDA for premarket approval ("PMA process"), or qualify for one of two exceptions to this time-intensive regulatory review. The PMA process involves close scrutiny of the device by the FDA, and approval requires that the FDA conclude that it has received "reasonable assurances of [the device's] safety and effectiveness" from the manufacturer. *Id.* § 360c(a)(1)(C). To that end, manufacturers must provide the FDA with samples of the device, an outline of the device's components, a description of the manufacturing process, copies of the proposed labels, and various other information. *See* 21 C.F.R. § 814.20(b). The FDA then reviews such submissions for an average of 1200 hours before either approving or disapproving the device. *Id.* §§ 812.1–.150; *see also Mitchell v. Collagen Corp.*, 126 F.3d 902, 905 (7th Cir.1997).

Kemp v. Medtronic, Inc., 231 F.3d 216, 221 (6th Cir. 2000).

violated a particular federal specification referring to the device at issue.'" *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (*quoting Ilarraza v. Medtronic, Inc.*, 677 F.Supp.2d 582, 589 (E.D.N.Y.2009)). "'To properly allege parallel claims, the complaint must set forth facts 'pointing to specific PMA [FDA premarket approval process] requirements that have been violated.'" *Id.* (*quoting Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1301 (D.Colo.2008)).

In the underlying case, Schmidt focuses his Amended Complaint solely on asserting parallel claims under Ohio Revised Code §§ 2307.75 *et seq.* and 2307.78 *et seq.* generally. Schmidt does not identify the specific FDA requirement that is alleged to have been violated or the specific, parallel Ohio requirement. Instead, Schmidt makes the general legal conclusion that Medtronic and Boston Scientific's "…failure to comply with relevant Federal statutes and regulations pertaining to the cardiac devices" proximately caused him harm. Doc. 27 at ¶¶23. 37, 42. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to overcome a motion to dismiss. *Iqbal*, 556 U.S. at 677-79. As such, Schmidt's mere conclusory statements that Medtronic and Boston Scientific have failed to comply with federal statutes and regulations are insufficient for the purposes of Rule 8 and the requirements of *Iqbal* and *Twombly*.

Schmidt argues that he is unable to identify the federal provisions or the Ohio statutes that have been violated without discovery. However, Schmidt has sufficient information accessible without discovery to identify both the federal provision and state statutes. Schmidt has exclusive control over his medical records, which would include device information, along with access to the FDA website, which describes in detail the PMA approval process for the ICDs, leads and related components that are within the public domain. Schmidt could have, with

reasonable effort, described the federal requirements that have allegedly been violated and any parallel state statute. Other courts have likewise determined that a general argument for more discovery does not necessarily save a defective pleading. *See Johnson v. Eli Lilly and Co.*, 1:14CV453, 2015 WL 1120009 (S.D. Ohio March 12, 2015) (dismissing plaintiff's claim for defective manufacturing/construction even though plaintiff argues she could not identify a specific manufacturing defect without discovery and plaintiff alleged drug was not made in accordance with manufacturer's specifications or standards); *see also Frey v. Novartis Pharmaceuticals Corp., et al.*, 642 F.Supp.2d 787 (S.D. Ohio 2009).

Finally, it appears undisputed by the parties that Schmidt's negligence claims are preempted. *Reigel,* 552 U.S. at 320. It is also undisputed that the negligence claims are abrogated by the Ohio Product Liability Act. Schmidt does not oppose the defendants' motions on this negligence issues. As such, the Court hereby dismisses Schmidt's negligence claims as being preempted.

Because Schmidt has already had an opportunity to amend the Complaint to make it compliant with Rule 8, *Iqbal*, and *Twombly*, the Court hereby DISMISSES the Amended the Complaint.

IV. CONCLUSION

The Court finds that Plaintiff's Amended Complaint fails to comply with the requirements of Rule 8 and the Supreme Court's decisions in *Iqbal* and *Twombly*. As such, the Amended Complaint is hereby DISMISSED.

IT IS SO ORDERED.

DATE: March 31, 2016

/s/ John R. Adams
Judge John R. Adams
UNITED STATES DISTRICT COURT